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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,637	05/04/2001	Dov Malonek	20066.79	6911

26418 7590 12/10/2004

REED SMITH, LLP
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,637

Applicant(s)

MALONEK ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-33,36-48,50-61 and 63-73 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19, 41-45/(41-44) is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/1/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5-18, 20-33, 36-40, 45/(5-18, 20-33, 36-40), 46-48, 50-61, and 63-73 .

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/1/04 has been entered.

Election/Restrictions

Claims 46-48 and 50-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/26/03.

Newly submitted claims 5-18, 20-33, 36-40, 45/(5-18, 20-33, 36-40), and 63-73 and directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are a subcombination of the originally presented combination claims. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require an electrode with a capacitance of 300 microfarads. The subcombination has separate utility not requiring suitable control means but as a sensing electrode connected to an amplifier.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 5-18, 20-33, 36-40, 45/(5-18, 20-33, 36-40), and 63-73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague since it depends from a canceled claim. It is unclear which claim the claim depends from.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In each of the references used for the rejections below, the references provide some sort of means for suitable control (the claimed “suitable control means” has only been given a function of means for suitable control) since the leads and electrodes deliver a pulse or no pulse from a connected implantable pulse generator.

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Claims 41-45/(41-44) are rejected under 35 U.S.C. 102(b) as being anticipated by Pless et al (5456706). Pless is capable of meeting the functional use recitations presented in the claims since he provides an electrode that is capable of delivering a stimulation pulse and the electrode will therefore be capable of delivering an energy level lower than a stimulation pulse.

Claims 41-45/(41-44) are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffmann et al (5534022). Hoffmann is capable of meeting the functional use recitations presented in the claims since he provides an electrode that is capable of delivering a stimulation pulse and the electrode will therefore be capable of delivering an energy level lower than a stimulation pulse.

Claims 41-45/(41-44) are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kieval (5814079).

Claims 41-45/(41-44) are rejected under 35 U.S.C. 102(b) as being anticipated by Noren et al (5649966). It is inherent that Noren contain some type of connection means for connecting the electrodes to the control means. Such connection being a connector, a conductor, and/or the lead itself. In addition, Noren is capable of performing the functional use recitations presented in the claims since he provides an electrode that is capable of delivering a stimulation pulse and the electrode will therefore be capable of delivering an energy level lower than a stimulation pulse.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41-45/(41-44) are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scherlag (5083564).

Scherlag uses conventional leads with an electrode separation being one mm to ten mm. In addition, Scherlag states that the system can be incorporated into an implantable system with sensing and delivering of the pulses and will inherently have a control means to control the stimulation. In addition, Scherlag inherently contains connection means to connect the electrodes to the control means. Such connection being a connector, a conductor, and/or the lead itself. In addition, Scherlag is capable of performing the functional use recitations presented in the claims.

In the alternative, Scherlag discloses the claimed invention except for the control means to receive the signals and determine the parameters of the electric field and deliver the field to the electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable stimulator as taught by Scherlag, with the control means to receive the signals and determine the parameters of the electric field and deliver the field to the electrodes since it was known in the art that implantable devices use a control means

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to receive the signals and determine the parameters of the electric field and deliver the field to the electrodes to provide an automated system that controls the device to sense heart signals, determine electric pulse parameters, and deliver the pulses to the electrodes that does not require constant intervention from a physician.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The argument that the electrode is designed and optimized to supply therapeutic signals having energy in a non-excitatory electric field range and is therefore new and inventive is not persuasive. The size of the electric field being delivered (or sensed) has NOT been claimed, only that the electrodes are capable of delivering this field. The field/electrode could be numerous sizes for different hearts, such as a human heart, whale heart, a mouse heart, etc. Also, different tissues and different tissue sizes have different non-excitatory thresholds. In addition, any electrode that delivers a pacing pulse or defibrillation pulse is also capable of delivering a pulse that is smaller than a pacing/defibrillation pulse (a "non-excitatory electric field") since nothing will prevent the electrode from delivering a smaller pulse. The argument that a great deal of innovative skill is necessary to balance and optimize the electrodes is not persuasive since the factors, elements, and skill to optimize the electrodes have not been claimed. The argument that the size of the electrodes influences the final performance is not persuasive since the size of the electrodes has not been claimed. In addition, the claiming of the size of the electrodes would most likely be found in the prior art since the size of the non-excitatory field or the particular tissue being

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stimulated has not been defined. Different tissue and different tissue sizes have different thresholds for non-excitatory fields.

The argument that the electrode systems of the prior art can not be used to apply a localized signal is not persuasive since the claims do not contain any limitations to applying a localized signal but only that the electrodes be "either" unitary or in close proximity. In addition, the range or extent of the localized signal or proximity has not been specifically defined except in those claims where the distance between the electrodes are recited. The argument that the large surface area of the electrodes mean that a high enough current density cannot be attained to produce non-excitatory signals for a protracted period of time without depleting the energy source of the device is not persuasive since the amount of time the device operates has not been claimed.

The prior art used in the rejections above show multiple different leads and electrodes being used to deliver non-excitatory stimulus pulses. The electrodes ranging from large surface area defibrillation electrodes to pacing and sensing electrodes from conventional implantable leads. In addition, the prior art cited show the details that are well known in the art for the 103 rejections related to the specifics of the lead and electrodes. It is suggested to incorporate most, if not all, of the specifics of the lead and electrodes into claims that also contain control means to deliver the non-excitatory pulses. Although, those claims will need to be further searched and examined.

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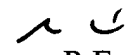
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

12/8/4

GRE
December 8, 2004